

Chapter 19

Medicaid Provider Manual

January 2011

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PHARMACY SERVICES

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19.1 PHARMACY SERVICES

19.1.1 Description

The Medicaid program pays for medically necessary and non-experimental drugs and pharmacy services with certain limitations.

19.1.2 Amount, Duration and Scope

Licensed pharmacies may dispense formulary medications to clients. Pharmacy technicians may help prepare the prescriptions if supervised by a licensed pharmacist but the pharmacist must review all work and is responsible for the actions of the pharmacy technician. Licensed physicians or prescribers may administer or dispense formulary medications to their patients. Nursing staff under the prescriber's supervision may administer formulary medications.

19.1.3 Drug Formulary

19.1.3.1 General

- a) The Medicaid Drug Formulary is basically an open formulary with specific exclusions and limitations.
- b) Choices of drug products are based upon therapeutic efficacy, safety and economy from manufacturers participating in the federally required rebate program as described in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).
- c) Nothing in the formulary or general rules gives permission or is intended to encourage violation of state or federal laws or regulations.

19.1.3.2 Drugs

- a) Payments shall be made for drugs when dispensed to eligible clients within the following guidelines:
 - 1. When prescribed by a practitioner licensed by the state;
 - 2. For prescriptions prescribed by an out-of-state practitioner, state regulations regarding the filling of out-of-state prescriptions would apply including the requirement that the prescriber must be licensed in his/her own state;
 - 3. When the drug has been approved by the U.S. Food and Drug Administration (FDA) for the purpose for which it is prescribed for human use;

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4. When the drug can be expected to be of therapeutic value for the disease or condition under treatment; and

- 5. When the medication is covered by the program or prior authorization has been obtained from the Pharmacy Fiscal Agent.
- b) On rare occasions, a non-rebate manufacturer's product may be the only appropriate medication for the client's condition. In this case, the MQD Administrator must approve the prior authorization because no federal funding will be provided.
- c) Medications for inpatients of acute care facilities and patients undergoing renal dialysis are exempt from formulary restrictions. Drug claims for clients receiving renal dialysis must still be billed to other primary insurance such as Medicare, if applicable.
- d) When a Specific Brand is Required:
 - 1. When a Provider bills Medicaid for claims where Dispense as Written 1 (DAW 1) is required, although the statements "Brand Medically Necessary" or "Do Not Substitute" are preferred by the MedQUEST Division, other statements such as "Use BRAND", "Brand Only", "No Generics", "No Substitution" or "Dispense as Written" are acceptable when it is the clear intent of the prescriber that the dispensing of a Brand Name drug is medically necessary.
 - 2. A physician must specify that a specific brand is medically necessary for a patient. Preprinted or pre-stamped notations are not acceptable.
 - 3. The pharmacist receiving telephone requests must write on the face of the prescription, "Brand Specified by Dr.______", or similar wording, and sign their full name. The prescribing physician is to document in the patient's chart the brand specifically designated and the justification for the medication.

19.1.3.3 The Drug Use Review (DUR) Board

The DUR Board consists of appointed actively practicing physicians and pharmacists from various settings and one drug manufacturer representative. The Board meets when the Chair calls for a meeting to discuss retrospective drug utilization issues; prior authorization criteria, ongoing education and other drug related issues. The DUR Board is part of the Drug Use Review program required by Section 1927 of the Social Security Act. For more details, see Appendix 6, Drug Use Review Program.

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19.1.4 Exclusions

a) Certain combinations of drugs for which the pharmacological action of the components is subject to question or because of excessive costs are excluded.

- b) Drugs for the treatment of pulmonary tuberculosis or for Purified Protein Derivative (P.P.D.) conversion are excluded. Exceptions for chemoprophylaxis of tuberculosis with isoniazid for children are permitted based on the criteria listed in Appendix 6, Drug Coverage Criteria. Patients with pulmonary tuberculosis must be referred to Lanakila Health Center or Leahi Hospital on Oahu, or local health department tuberculosis clinics on neighbor islands.
- c) Drugs for the treatment of Hansen's disease are excluded and clients should be referred to the Department of Health's Hansen's Disease Program for medications provided free of charge.
- d) Drugs not approved by the FDA for the purpose for which it is being prescribed, as well as drugs deemed "less than effective" are not covered. Refer to periodic lists of "less than effective" (LTE) drugs which are commonly referred to as Drug Efficacy Study Implementation (DESI) 5 or 6 drugs. (See the Pharmacy Fiscal Agent's website for the current list of LTE drugs)
- e) Foods and food supplements are not considered drugs and are, therefore, excluded from the formulary. These require prior authorization and are billed using HCPCS codes.
- f) Natural, organic and herbal preparations are excluded.
- g) Products for cosmetic purposes, such as tretinoin (Retin-A) for skin improvement or Minoxidil (Rogaine) for hair growth, are not covered. However, their uses for pathological conditions, e.g., Minoxidil as an antihypertensive medication, are covered.
- h) Hypopigmentation agents such as Lustra, Solaquin, Esoterica and Nuquin HP are excluded.

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i) Fertility agents or those inducing ovulation are excluded.

- i) Vaccines for travel and vaccines provided by the Vaccines for Children Program (VFC) are excluded. Refer to the Immunization section, Chapter 6.
- k) Experimental drugs are excluded
- Treatments for erectile dysfunction in males such as, penile prostheses, etc. are excluded.
- m) Drug products supplied by manufacturers that do not participate with the CMS drug rebate program are not covered. Contact the Pharmacy Fiscal Agent by phone or through the website for the listing of drug manufacturers who participate with the CMS Drug Rebate Program.
- n) Androgens and estrogens for establishment or maintenance of gender reassignment (transsexual) are excluded unless the individual's sex was changed by court order. A diagnosis is required for all prescriptions and claims for estrogens and androgens when prescribed for patients under 40 years of age.

19.1.5 Limitations

19.1.5.1 General

- a) Anabolic steroids require approval on a Request for Medical Authorization DHS Form 1144B prior to dispensing. Refer to Appendix 4 for a sample of the form.
- b) Appetite suppressants (anorexics) require prior authorization. Information on the Request for Medical Authorization DHS Form 1144B must include the patient's weight and program for weight loss. (Refer to Appendix 4 for information about completing DHS Form 1144B.) Other types of weight loss products such as Meridia may have more specific prior authorization criteria. Please refer to the list of medications requiring prior authorization in Appendix 6 Drug Coverage Criteria or to the Pharmacy Fiscal Agent's website (listed in Appendix 1).

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c) Drugs for the treatment of specific disorders are payable without prior authorization when the diagnosis codes appear on the prescription and the claim. Refer to the Drug Coverage Criteria in the Pharmacy Fiscal Agent's website, listed in Appendix 1, for additional information.

- d) If prior authorization is required, but has not been obtained, the claim will be denied.
- e) The prior authorization requirement for designated medications is waived in certain instances for specified practitioner specialties. Psychiatrists may prescribe most atypical antipsychotics without prior authorization approval. Non-psychiatrists must obtain prior authorization for clozapine, olanzapine, risperidone, quetiapine and ziprasidone. Refer to the Drug Coverage Criteria in the Pharmacy Fiscal Agent's website, listed in Appendix 1, for additional information.
- f) Vitamins and minerals are excluded from the program except:
 - 1. Multiple vitamins taken during pregnancy or lactation. The acceptable diagnosis of "pregnancy" or "lactation" must appear on the prescription and the claim.
 - 2. Pediatric multiple vitamins, including those with fluoride, for children who are 12 years and younger.
 - 3. Vitamins for specific deficiencies, e.g., pernicious anemia, sprue, scurvy, beriberi, etc., for outpatients with prior authorization. Physical, laboratory or other findings establishing the diagnosis must be available in the prescribing physician's medical records.
 - 4. One multivitamin daily and orally without prior authorization, for patients in nursing facilities.
- g) Coverage of non-prescription drugs is limited. See the Pharmacy Fiscal Agents website listed in Appendix 1 for the Over the Counter (OTC) Formulary.
- h) For diabetic supply limitations, please refer to Chapter 10, DMEPOS.
- i) The maximum quantity of medication, which may be dispensed at one time for outpatients, is a 30-day supply or 100 eaches, or 50 gms or 50 mls, whichever is greater.

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j) If the estimated days supply exceeds thirty (30) days

- 1. And the drug prescribed is dispensed in the original, unbreakable, sole or smallest unit, the days supply may be entered as thirty (30) days; or
- 2. The prescriber orders a quantity that exceeds thirty (30) days but the smallest package would result in less than a thirty (30) day supply, the provider should dispense the smallest quantity that would exceed the thirty (30) days supply and enter thirty (30) days supply. Example: Prescriber orders two (2) albuterol inhalers seventeen (17) grams each. One (1) inhaler would not last thirty (30) days and two (2) inhalers would exceed the thirty (30) day limit. The provider may use thirty (30) days supply for the two (2) inhalers so two (2) dispensing fees are NOT charged per month.
- k) Lower cost therapeutically equivalent drug products must be dispensed if available in the marketplace and substitution is not prohibited by Part VI, Drug Product Selection of Chapter 328, HRS. The client may refuse the lower cost drug products but must pay the entire cost of the higher cost equivalent.

19.1.5.2 Medicare Issues

19.1.5.2.1 Medicare B Drug Program

- a) Medications that are covered by Medicare must be billed to Medicare first. Medicaid is always the payer of last resort.
 - 1. Insulin Used in Insulin Infusion Pumps

As of April 1, 2000, Medicare reimburses the following:

- The external ambulatory infusion pump for insulin,
- Injection, insulin
- Supplies for the insulin pump
- 2. Claims for the above items for clients with Medicare and Medicaid coverage who meet the Medicare criteria such as Type 1 diabetes and require multiple daily injections and glucose injections, must be billed to the Medicare Part B Durable Medical Equipment Carrier Regional Carrier (DMERC) first. If post-payment re-

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views by the Med-QUEST Division (MQD) show claims are being inappropriately billed to and paid by Medicaid, recovery of all allowances involved will be made.

- b) Other Criteria and Restrictions
 - See Appendix 6, Drug Coverage Criteria, or the Pharmacy Fiscal Agent's website, listed in Appendix 1, for additional information regarding Medicare coverage and Medicaid restrictions for such drugs as oral anti-cancer agents and immuno-suppressive agents, etc. See Appendix 3 for CMS 1500 billing guidelines for drugs provided in the practitioner's office.

19.1.5.2.2 Medicare Part D Prescription Drug Program (PDP)

With this Medicare benefit, the vast majority of the medications for clients who have both Medicare and Medicaid coverage are covered by Medicare. Medicaid FFS covers the drugs that Medicare is prohibited by federal law from reimbursing. These Medicare Part D "excluded" drug categories are listed below, along with clarification of coverage by the Medicaid FFS program.

- a) Drugs for anorexic, weight loss, weight gain:
 - Prior authorization (PA) is required for drugs indicated for weight gain, as Medicare Part D covers ONLY if the drugs are for patients with HIV/AIDS and/or cancer.
 - Other FDA weight gain related indications are covered.
 - 3. Medications for weight loss are covered with PA.
- b) Legend drugs for symptomatic relief of cough and cold, or solely cough:
 - Legend drugs for symptomatic relief of cough and cold are covered by Medicare Part D when they are used to treat medical conditions such as allergy, angioedema, bronchitis, etc. Therefore, effective with initiation of Part D on January 1, 2006, PA is required for these drugs that may be covered by Medicare. These drugs are:

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• Legend antihistamines/decongestant combinations and single products.

- Legend combination products containing antitussives/expectorants with antihistamines, decongestants, etc.
- 2. The medications that are not covered by Medicare Part D that MQD covers as usual are:
 - Legend medications used for relief of cough and cold symptoms only (such as guaifenesin, dextromethorphan, codeine, etc.).
 - Over-the-counter (OTC) products.
- 3. Prescription vitamins and mineral products:
 - Prenatal vitamins and fluoride must be billed to Medicare Part D.
- 4. Over-the-counter drugs:
 - The same medications currently covered by Medicaid FFS, except insulin which is covered by Medicare Part D.
- 5. Barbiturates. (covered by Medicaid FFS)
- 6. Benzodiazepines. (covered by Medicaid FFS)

19.1.5.2.3 Identifying PDP Enrollment for Dual Eligibility Clients

- a) Pharmacies have five ways of identifying PDP enrollment for individuals:
 - 1. Ask the individual to present their membership card or the assignment letter from Medicare identifying their plan;
 - Call the Medicare Pharmacy Line. The Center for Medicare and Medicaid Services (CMS) customer service representatives are available to identify the beneficiary's plan when provided with basic information. Pharmacies provide their National Provider Identifier (NPI) as well as Medicare Health Insurance Claim

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Number (HICN), Date of Birth, Beneficiary Name, Zip Code, Part A or B effective date, and gender. Upon completion of the search, CMS provides the drug plan name and, if requested, the effective date of Medicare Part D coverage. See Appendix 1 for current contact number.

- 3. Submit an E-1 (eligibility) query to the TrOOP facilitator. This transaction returns the phone number of the beneficiary's assigned plan.
- 4. Call CMS Part D Emergency Situation line, which is available 24 hours / 7 days a week. See Appendix 1 for current contact number.
- 5. Call Medicare Point of Sale Help Desk when no Part D coverage can be identified. See Appendix 1 for current contact number.
- b) The DHS Eligibility Verification Systems is not to be used to confirm Medicare Part D plan enrollment information.

19.1.5.2.4 Medication Plan Coverage and Billing Hierarchy

- a) Pharmacy coverage for Medicaid/Medicare dual eligible clients is provided through multiple programs. The hierarchy continues to affirm that Medicaid is the payer of last resort.
 - 1. When the drug is covered by Medicare Part B:
 - The provider bills Medicare Part B for the drug using an appropriate Healthcare Common Procedure Coding System (HCPCS) code.
 - Medicare Part B then pays for the drug.
 - 2. Medicaid covers the Medicare Part B co-payment and applicable deductibles thusly:
 - The Medical Fiscal Agent accepts and reimburses the co-payment and applicable deductibles for Medicare Part B drug claims; and
 - 3. Claims for co-payment and applicable deductibles are accepted in two (2) ways:

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Claims are "crossed over" electronically by Medicare Part B; or

- The provider may submit a hard copy claim to Medicaid via the Medical Fiscal Agent with an Explanation of Medicare Benefits (EOMB).
- 4. When the drug is covered by Medicare Part D:
 - The Medicare Prescription Drug Plan (PDP) is responsible for the claim;
 - Medicaid does NOT cover a prescription when the Medicare PDP is responsible for the therapeutic class.
- 5. A drug is covered by Medicaid when:
 - Medicare Part B is not responsible for coverage; AND
 - Medicare Part D is not responsible for the therapeutic class coverage;
 AND
 - It is on the list of Medicaid Covered Drugs Excluded From Medicare Part
 D. See Appendix 6 for current list.

19.1.5.2.5 Transition Plans

- a) PDP First Fill Process (Dual Eligibles Enrolled in a PDP)
 - 1. All Medicare Part D plans must have a transition process for all new Medicare Part D individuals enrolled in their PDP. The "First Fill " allows the individual to receive drugs not on the PDP's formulary, thus, allowing time for the required PDP- patient-doctor collaboration to determine whether a formulary drug can be prescribed. If not, the patient-doctor can follow the PDP's "Exception process" to determine whether a non-formulary drug can be covered. Through this process, an individual newly enrolled in a PDP who presents at a pharmacy with a prescription for a drug that is NOT on the PDP's formulary leaves the pharmacy with a "First Fill" for that drug. The individual's PDP is responsible for the payment of the cost of the drug. Pharmacy questions regarding this process should be directed to the member's specific Part D PDP.
- b) Medicare Part D Contingency Plan (Dual Eligibles Not Enrolled in a PDP)
 - 1. The Medicare Part D Contingency Plan enables a Full Benefit Dual Eligible (below 100% of the Federal Poverty Limit), with evidence of both Medicaid and

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Medicare eligibility, who is NOT currently enrolled in a PDP, to receive a 14 day supply of his/her prescription drugs. The POS Contingency Plan does NOT apply to a Dual Eligible who is a Qualified Medicare Beneficiary (QMB), Specified Low income Medicare Beneficiary (SLMB) or a Qualified Individual-1 (Q1-1). Through this process, a dual eligible "newly or not yet enrolled" in a PDP who presents at a pharmacy with a prescription for a drug leaves the pharmacy with a 14 day supply of their drugs.

- 2. The claim for the cost of the drug is submitted to the Medicare Part D Contractor. For assistance call the Help Desk. See Appendix 1 for the current contact number.
- 3. For urgent and emergencies situations including situations in which a Dual Eligible on chronic medication has little or no supply of the medication to use when the pharmacy is unable to process a claim due to insufficient plan/enrollment/eligibility information, call the Medicare Hotline (see Appendix 1) and inform the agent that this is an emergency situation. Emergency calls will be referred to the CMS Regional Office for expedited handling. The process is initiated as part of the billing hierarchy or when the situation warrants immediate action because (following the hierarchy) the health or safety of the Dual Eligible would be compromised.
- 4. For each of the above situations, the Medicare Part D co-payment for generic/brand drugs for Dual Eligible individuals enrolled in the Hawaii State Pharmacy Assistance Program (SPAP) is filed through the Pharmacy Fiscal Agent, if they are enrolled in one of the qualifying CMS Standard Benefit Plans (see below, State Pharmacy Assistance Program). Eligibility for SPAP enrollment can be identified through the presentation of a teal colored "Smooth Transitions" card or by calling the Pharmacy Fiscal Agent Help Desk. See Appendix 1 for the current contact number.

19.1.5.2.6 State Pharmacy Assistance Program

- a) The State Pharmacy Assistance Program (SPAP) is a state-funded program that pays the Medicare Part D co-payments for qualified Hawaii residents. It is a three– tier program of plans for individuals whose household income does not exceed 150% of the Federal Poverty Level (FPL). Plans are delineated at up to 100% of FPL, 101-135% of FPL and 136-150% of FPL. An eligible individual must:
 - 1. Be a resident of Hawaii

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2. Be age 65 or older or Disabled and eligible for Medicare

- 3. Have a household income that does not exceed 150% of the Federal Poverty Level (FPL)
- 4. Not have assets that exceed the limits set by Medicare Modernization Act of 2003
- 5. Not be a member of a retirement plan who is receiving a benefit from the Medicare Part D Program
- 6. Not be enrolled in a public assistance program that provides drug benefits other than those provided by Medicare Part D
- 7. Not be enrolled in a private sector plan or insurance providing payments for prescription drugs
- b) Only Dual Eligibles who have incomes at or below 150% of the FPL are automatically enrolled in the SPAP. All other Dual Eligibles with incomes above 150% of the FPL are not eligible for the SPAP. All other individuals in the community who do not receive Medicaid benefits must submit an application.
- c) Coverage for SPAP benefits begins when the individual is enrolled in a one of the Medicare Part D Standard Prescription Drug Plans or Medicare Advantage/Other Health Plans. No SPAP benefit will be available if the Dual Eligible whose income is equal to or below 150 % of the FPL is enrolled in any other PDP or Medicare Advantage/Other Health Plan. See the Pharmacy Fiscal Agent website (Appendix 1) for a complete listing and description for all SPAP plans.
- d) To process claims for the SPAP, the Department of Human Services has established a separate claims process through the Pharmacy Fiscal Agent. To electronically bill the claim, the pharmacy must submit the following information in the identified fields:

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1 NCPDP Field	2 Enter for POS sub- mission	3 Description
308-C8	8	Third Party Liability (TPL) co-pay only
478-H7	>0	
479-H8	99	
480-H9	\$ amt generic/brand	The amount of the TPL co-pay

- e) Special Handling of Denied SPAP Claims
 - 1. If a client's SPAP claim is rejected for expiration of SPAP, the pharmacy shall:
 - Request the client's Medicaid identification number;
 - Ask the client to provide their Medicare Part D PDP membership card or Medicare letter of auto-enrollment;
 - Submit a POS E-1 query to determine plan auto-enrollment or call the Medicare Call Center Pharmacy Helpline, 24 hours, 7 days a week and provide the client's Medicare number; See Appendix 1 for the current contact number.
 - Contact Med-QUEST Call Center 7:45 a.m. to 4:30 p.m., Monday through Friday. The call center confirms the Medicaid identification number and, if eligible for SPAP benefits, updates the file the following business day, allowing the pharmacy to process the SPAP claim. See Appendix 1 for the current contact number.

19.1.5.3 Emergency Issues

Pharmacists may be required to make emergency calls to the long-term care facility. An emergency call shall be one that cannot be delayed, i.e. non-routine call to the patient of a facility by the pharmacist in a life-threatening situation. All other services shall be handled during the pharmacist's routine visits whenever possible. A maximum of 4 visits per month may be paid at a rate per call for each 100 beds in the facility at the time the services are rendered. Any fraction of one hundred beds shall be prorated accordingly. For facilities with less than 25 beds at the time services are rendered, pharmacists may charge up to one full emergency call per month.

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19.1.5.4 Medical Supplies

a) Medical supplies, such as insulin needles and syringes or sick room supplies, are not included in the formulary because they are not drugs; however, they are covered by the program when prescribed by a provider.

b) Information about medical supplies can be reviewed in Chapter 10, DMEPOS.

19.1.5.5 Clinical Screening, Counseling and Patient Profiles

- a) Pharmacy providers must perform prospective drug use review, which includes the following elements:
 - 1. Perform clinical screening on all fee-for-service Medicaid prescriptions.
 - 2. Offer counseling on all prescriptions new and refills.
 - 3. Maintain appropriate documentation.
 - 4. Maintain patient profiles.

See Appendix 6, Prospective DUR, for more detailed criteria and requirements.

19.1.5.6 Drug Mis-Use/Over-Utilization

- a) All providers are urgently requested to assist the Medicaid program in identifying cases of drug mis-use or over-utilization. Information should be transmitted to DHS/MQD/CSO Officer. Refer to Appendix 1 for the address and telephone number.
- b) The program may restrict clients who are over utilizing controlled substances or who are receiving unusually extensive medical services from multiple providers to one primary care provider and pharmacy.

19.1.5.7 Drug Services - Covered with limitations

- a) Drugs must be prescribed by a licensed prescriber and be medically necessary for the treatment of the condition for which it was prescribed.
- b) The maximum quantity of medication which may be dispensed at one time is as follows:

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1. Patients discharged from hospitals or acute care facilities may receive up to a 7-day supply of take home medications. This must be billed as part of the inpatient care. Refer to Outpatient Hospital Pharmacy, Section 19.2.

- 2. Outpatients may receive the larger of a 30-day supply, 50 gms, 50 mls or 100 each. All formulary guidelines and restrictions apply.
- c) Quantities exceeding these limits must be approved by the Pharmacy Fiscal Agent on the Request for Medical Authorization DHS Form 1144B.
- d) Drugs approved by prior authorizations on DHS Form 1144B must also be dispensed within guidelines a) and b) above unless specifically approved for amounts exceeding the maximum limits.
- e) For drugs used during treatment in the emergency room, take home drugs for outpatients treated in the emergency room, and drugs provided to waitlisted long-term care patients; see section 19.2, Hospital Outpatient Pharmacy.
- f) Additional limitations are described in Section 19.1.3, Drug Formulary.

19.1.5.8 Tamper Resistant Prescription Pads

- a) Effective October 1, 2008, all FFS Medicaid prescriptions that are either handwritten or printed from an Electronic Medical Record (EMR) or from an ePrescribing application must contain at least one (1) feature from each of the three (3) categories of tamper resistance as outlined in Best Practices for Tamper Resistant Prescriptions.
 - 1. Best Practices for Tamper Resistant Prescriptions can be found at the Pharmacy Fiscal Agent website. (Appendix 1)
 - The listing of the security features and descriptions on all prescriptions is STRONGLY recommended so the pharmacist can easily identify them and determine compliance. There is no single format, size or color for the security prescription forms. Additional expensive safety features such as unique batch numbers and holograms may be used.
 - 3. EMR or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant, provided they contain at least one (1) feature from each of the three (3) categories of tamper resistance.

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b) Prescriptions prescribed by a dentist for Medicaid FFS clients and for managed care clients that are telephoned, faxed or ePrescribed remain exempt from these tamper resistance requirements. Prescriptions for managed care clients except those handwritten by dentists do NOT require TRPP.

c) If the original prescription was presented to the pharmacy for filling prior to October 1, 2008, the refills of that prescription do not need to be on TRPP with all three (3) characteristics. Prescriptions written between April 1 and October 1, 2008 need to contain only one (1) of the three required characteristics.

19.1.5.9 State Legislative Initiatives

- a) Psychotropic Medications
 - 1. HRS 346-59.9 requires Medicaid provide equal access to anti-psychotic medications to all Medicaid clients for the treatment of mental or emotional disorders when these medications are prescribed by a licensed psychiatrist, physician or advance practice registered nurse (APRN) with prescriptive authority.
 - The law requires that Medicaid cover therapeutic agents approved by the FDA for the treatment of mental and emotional conditions. Thus MQD retains or may establish prior authorization (PA) requirements or other restrictions for non-FDA approved indications, or for FDA approved agents for non-mental and nonemotional disorders.
 - State Maximum Allowable Costs (SMACs), Federal Upper Limits (FULs), current quantity limits and mandatory generic edits remain in place. PAs for brand products are still required if higher reimbursement is requested. Claims will continue to deny due to possible Medicare or other third party liability (TPL) coverage.
 - Hawaii Medicaid FFS requests ICD-9 diagnosis codes be submitted on claims for psychotropic agents to evaluate prescribing trends through focused drug utilization reviews.
- b) HIV/AIDS, Hepatitis C and Transplant Immunosuppression Medications

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 HRS 346-351 mandates coverage for FFS Medicaid clients for therapeutic agents authorized/indicated by the FDA for use in the actual treatment of HIV/AIDS, Hepatitis C and transplant immunosuppression

- Uses of these agents for FDA approved or non-FDA approved therapies other than those indicated in the law may be subject to PA requirements as deemed appropriate by MQD.
- Claims will continue to deny due to possible Medicare or other third party liability (TPL) coverage.

19.1.6 Authorization Requirements

19.1.6.1 General Prior Authorization Information

- a) Approval is required before a non-formulary drug, an excluded drug, or a restricted drug with limitations, is reimbursed.
- b) A request for prior authorization must be submitted by the prescriber or the pharmacy provider on the Medical Authorization form (DHS Form 1144B). The use of any unauthorized form is not acceptable.
- c) The prescriber is responsible for completing the following information: drug prescribed, strength, daily dose and quantity, as well as, diagnosis, medical justification, length of therapy and provider signature.
- d) The DHS Form 1144B must also include the drug NDC number and NCPDP units, and the supplier's information. See the Pharmacy's Fiscal Agent's website listed in Appendix 1 and Appendix 4 for forms.
- e) Refer to Appendix 6, Drug Coverage Criteria for additional information regarding medications that require prior authorization.

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f) A cover sheet must accompany each DHS Form 1144B with the name, telephone number, and facsimile number of the supplier or prescriber and the name of the contact person at the supplier's or prescriber's office. These must be sent by facsimile or mailed to the Pharmacy Fiscal Agent. The fax number and mailing address are in Appendix 1.

- g) The Pharmacy Fiscal Agent shall respond to requests for prior authorization of drugs submitted on the "Request for Medical Authorization" DHS Form 1144B within twenty- four (24) hours of receipt. A fax cover page with the reviewer's first name, the approval period, the PA number or the reason for denial/deferral with a copy of the DHS Form 1144B shall be faxed back to the supplier and/or prescriber. The Pharmacy Fiscal Agent will respond with its decision:
 - An approval; if duplicate or overlapping authorization requests are for a drug which is medically necessary and covered by Medicaid, the first complete authorization received by the Pharmacy Fiscal Agent will be approved and an authorization number will be provided by fax to the supplier and/or prescriber if applicable. Approvals on DHS Form 1144B may be for up to 1 year from the date of approval.
 - A denial; if duplicate or overlapping authorization requests are for a drug which is medically necessary and covered by Medicaid, the second or later complete authorization received by the Pharmacy Fiscal Agent will be denied.
 - 3. Or a deferral; when the justification submitted is insufficient for either an approval or denial or if the form is incomplete (i.e., the physician's signature and date of signature, the supplier's name, signature, date of signature and National Provider Identifier (NPI).)
- h) Do not mail the original DHS Form 1144B to the Pharmacy Fiscal Agent. The supplier shall retain, for its records, the original DHS Form 1144B form signed by the prescriber. If the prescriber retains the original DHS Form 1144B, the supplier shall have a copy on file.
- Requests for vendor/supplier changes shall only be honored under the following circumstances:
 - 1. The original approval has expired.

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2. If the original supplier shared the PA number with the new supplier, it may be used to fill the prescription. IF NOT, a new PA is required.

NOTE: The Pharmacy Fiscal Agent cannot release the original PA number from another pharmacy PA.

- j) A new PA is required for the following:
 - 1. If the quantity is specified in the current PA, such as 30 tablets/month, then a new PA is required for changes in quantity (e.g. a change in directions for the same strength).
 - 2. If a new strength is prescribed for the same drug, then a new PA is required.
 - NOTE: PA limitations may be defined by the prescriber's directions. If the quantity or days supply is limited, the claim denies once the quantity or days supply is exceeded. A new PA is needed for any increase in the amount or days supply.

19.1.6.2 Emergency Dispensing of Drugs which Require Prior Authorization

- a) In an emergency situation, suppliers can dispense up to a seventy-two (72) hour supply of an outpatient prescription drug which requires prior authorization under the conditions listed below: The situation must be a true emergency such that the consequence of delaying the dispensing of the drug by 24 to 72 hours results in a high probability of serious adverse effects on the person's health. Serious adverse effects are hospitalization, medically necessary emergency room care, and loss of bodily function or life.
 - 1. The dispensing of the 72 hour emergency supply of drugs applies ONLY TO OUTPATIENT PRESCRIPTION DRUGS from manufacturers that participate in the Drug Rebate Program and for drugs that are NOT determined to be less than effective (LTE) (DESI 5 and 6). See the Pharmacy Fiscal Agent's website for LTE drugs and for information on the Drug Rebate Program. The website address is listed in Appendix 1.
- b) Such a prescription is presented to a pharmacist for filling at a time when the prescribing physician cannot be reached to authorize medication changes and delayed receipt of the medication will be extremely detrimental to the patient's health. Examples may include:
 - 1. A similar medication covered by the program is not available to the community and to delay would seriously endanger the patient's life.

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2. There is no similar medication available without prior authorization or the patient has a documented intolerance for the similar agent. (Example: Patient has an intolerance for cimetidine and must take ranitidine.)

- 3. An emergency supply of a specific brand name drug may be dispensed if the patient's physician has previously documented that the patient is unable to use a generic form of a drug (which does not require prior authorization) because of an allergy or history of a serious adverse reaction to the generic drug.
- c) The following procedures should be used for emergency dispensing of drugs:
 - 1. A DHS Form 1144B form must be completed by the supplier and submitted to the Pharmacy Fiscal Agent following the steps outlined above and similar to Section 19.1.6.1. In lieu of the prescriber's signature, the words "emergency dispensing" must be written in the signature space on the claim form. In addition, "emergency dispensing," the date, time, and justification for dispensing of the drug must be entered under the name of the drug on the claim form, and also documented on the prescription.
 - 2. After the PA desk of the Pharmacy Fiscal Agent's call center issues a verbal PA approval, the claim can be processed via POS.

19.1.6.3 Processing of Claims for Non-Rebate Drugs

- a) Non-rebate drugs
 - A non-rebate drug is occasionally covered if there is no rebate drug which adequately replaces the therapeutic effect of the non-rebate drug and if it is medically necessary.
 - 2. If a claim submitted to the Pharmacy Fiscal Agent is denied as a non-rebate drug, the provider receives notification.
 - 3. If the prescriber wishes to pursue this further, the PA request DHS Form 1144B must include additional information:
 - Diagnosis
 - List of formulary drugs tried and failed OR
 - List of reason(s) formulary drugs are not appropriate.
 - (The current drug criteria can be viewed at the MQD website, see Appendix 1.)
- b) Process:

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Fax the completed PA request DHS Form 1144B including the additional information to the Pharmacy Fiscal Agent with "ESCALATE FOR RECONSIDERATION" written on the top of the form DHS Form 1144B. (See Appendix 1 for the fax number.)

- 2. The Pharmacy Fiscal Agent reviews the DHS Form 1144B for completeness and formulary drugs used, then, with recommendations, faxes the DHS Form 1144B to the MQD Consultant Pharmacist at 808-692-8131.
- 3. The Pharmacy Fiscal Agent notifies the provider of MQD's decision.
- 4. Claims for non-rebate drugs cannot be processed electronically or by POS; they must be billed by hard copy, manually. The PA number authorizing the non-rebate drug must be notated on the DHS 204 claim form or CMS1500 form and addressed to the Pharmacy Fiscal Agent as indicated in Appendix 1.

19.1.6.4 Retro-PA Considerations

- a) If a provider is requesting a PA more than 30 days after a medication was given to the client from a POS environment (or 120 days when hard copy billing is used), the following information must be submitted for PA consideration:
 - 1. Diagnosis,
 - 2. Justification,
 - 3. Date medication given to the client,
 - Date of billing and
 - 5. Reason for LATE request for PA.

b) Process:

- 1. Fax the completed PA request Form 1144B including the additional information to the Pharmacy Fiscal Agent with "FOR CONSIDERATION" written at the top of the DHS Form 1144B.
- 2. The Pharmacy Fiscal Agent reviews the DHS Form 1144B for completeness and formulary drugs used, then, with recommendations, faxes the DHS Form 1144B to the MQD Consultant Pharmacist at 808-692-8131.
- 3. The Pharmacy Fiscal Agent notifies the provider of MQD's decision.
- 4. If approved, claims can be processed hard copy, electronically or by POS with the PA number given for the retro-PA.

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19.1.6.5 Specific Brand Product

Prior Authorization is generally required for payment for a specific brand product for a multiple source drug when the allowance is limited by the most current FUL (federal upper limit) price. See CMS's website (listed in Appendix 1) for drugs on the FUL price list. Providers should indicate that at least two generic drugs have been tried and were not effective or have caused adverse effects. Providers may contact the Pharmacy Fiscal Agent for a listing of the FUL prices if the internet is not accessible.

19.1.6.6 Other Prior Authorization Issues

- a) Unless specifically stated, prior authorization requirements of a class of drugs (example: non-sedating antihistamines, atypical antipsychotics) apply to all NEW drugs added to the class and not specifically referred to in a Medicaid memorandum.
- b) Prior authorization requirements have been waived when certain classes of drugs are prescribed by physicians with specific specialties. The waiver given to these specific specialties applies to new drugs added to the same class and may not be specifically referenced in a Medicaid memorandum. See the Pharmacy Fiscal Agent's website listed in Appendix 1 for the most current information. See "Drug Coverage Criteria" in Appendix 6 or in the Pharmacy Fiscal Agent's website for a listing of practitioner specialties and other criteria. Additional information such as diagnosis codes may also be required.
- c) Medications dispensed in excess of 100 each (tablets or capsules) or a 30 day supply whichever is greater require prior authorization except for the following:
 - 1. Liquids or sprays or inhalers which may be dispensed up to 50 mls, 50 gms or a 30-day supply whichever is greater, or
 - 2. Birth control pills which may be dispensed for up to three cycles.
- d) When a drug billed on a hard copy claim requires prior authorization, these claims must be submitted timely and need to be checked prior to dispensing for the following:
 - 1. PA approved if applicable;
 - 2. Participating rebate manufacturer; and

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3. Non-DESI product

- e) Refer to the Pharmacy Fiscal Agent's website under the Drug Coverage heading and PA criteria; under the Communications heading for the Drug Rebate report and the DESI listing. Providers without Internet access may contact the Pharmacy Fiscal Agent's Help Desk for a printed copy. The website and phone number are listed in Appendix 1.
- f) Prior authorization for medical supplies, durable medical equipment (DME), orthotic devices and prosthetic devices are not submitted on the same DHS Form 1144B with the outpatient prescription drugs. See Chapter 10, DMEPOS. Submit claims on DHS Form 1144 to Medical Fiscal Agent for review. See Appendix for fax number.
- g) The 24-hour return time does not apply to authorizations for enteral and parenteral nutrition as these therapies are generally considered to be medical supplies/durable medical equipment (DME), are coded primarily with HCPCS codes and are subject to the DME authorization guidelines.

19.1.6.7 Automated PA

- a) The Pharmacy Fiscal Agent oversees a system of clinical edits, which can provide an automated PA. This is an electronic enhancement to current claims processing at POS to minimize prior authorization (PA) requests for selected drugs and/or therapeutic categories. Beginning August 13, 2006, clinical criteria will be applied to:
 - 1. Selected COX II inhibitor
 - 2. H2 receptor antagonists (H2RAs)
 - 3. Proton pump inhibitors (PPIs)
 - 4. Sedative-hypnotics.
- b) The automated PA process involves the following steps:
 - The MQD establishes clinical criteria based upon therapeutic efficacy and safety. These criteria are posted on the MQD FFS Pharmacy Program website. See Appendix 1.

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2. When a claim is submitted via POS, it is subject to clinical edits. The system checks the diagnosis entered on the claim, and the client's available Medicaid drug and medical claims histories to determine whether the client's condition meets the criteria.

- If the client's drug and/or medical claims histories meet the criteria, the claim continues to the next step in the POS system without the need of additional PA documentation.
- 4. If the client's drug and/or medical claims histories do NOT meet the criteria, the pharmacy receives a text message indicating that providers may call into the Pharmacy Fiscal Agent Call Center or a PA request (DHS Form 1144B) is completed. The DHS Form 1144B form is available on the Pharmacy Fiscal Agent website. The prescriber and pharmacist may intervene via telephone with additional information not identified in the client's available Medicaid drug and medical claims histories, to allow the claim to continue processing. An approval number is provided if criteria are met and the claim is resubmitted to process.

Note: Although this system may cause a claim to reject, this is NOT to be considered a PA denial. A DHS Form 1144B form may be submitted for all PA requests, citing appropriate references for the additional documentation.

Note: PA requests for drugs that are NOT included in this system will continue to require DHS Form 1144B submission for review.

The automated PA system, along with the Preferred Drug List (PDL) helps optimize the use of program funds while ensuring access to care through the therapeutically prudent use of drugs.

19.1.7 **Billing**

19.1.7.1 General Pharmacy Billing Policies

- a) The National Council for Prescription Drug Programs (NCPDP) standard billing units are required for all drug claims. Metric decimal quantities are to be submitted on all claims for medications.
- b) There are three types of billing units: each, milliliters and grams. There are very few exceptions to the use of these three units including, but not limited to, Herceptin, which is billed by the number of milligrams and human antihemophilic factor, which is billed by the number of units.
- c) The proper billing units for a drug can be obtained from the following sources: First Data Bank software, the Red Book and the drug manufacturer.

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d) The NCPDP units assigned to a NDC number may not be the same as the units assigned to the drug's Healthcare Common Procedural Coding System (HCPCS) alpha numeric code. The units assigned to a HCPCS code should not be used for a NDC number without verifying that the units are correct.

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19.1.7.2 Clarification of Decimal Units Billing

- a) The proper billing of units for Medicaid drug claims requires decimal quantities.
- b) For software systems that bill by decimal or whole number quantities, the provider's software manual and/or vendor should be consulted to determine the decimal capacity of the provider's computer's billing system for Point-of-Sale (POS) electronic transmissions.
- c) If the provider's system does not accept decimal quantities (because it is a whole number system), then claims for these units need to be billed manually for the decimal quantity.
- d) It is not an option to round up the decimal to a whole number. It is not an option to bill it incorrectly via electronic transmission by POS. The drug claim must be billed manually to correctly indicate the decimal quantity. The billed price must be accurate on a decimal quantity basis regardless of the quantity specified in the nondecimal units field, when entering it into your whole number system.
- e) Once a drug claim is submitted with incorrect information and the provider has knowingly submitted the claim with incorrect information, MQD shall consider this fraudulent billing.

Examples follow:

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Product			Quality Dispensed	Proper Billing of Units	
Name	NDC No.	Size		Decimal System	Whole Num- ber System
Beclovent ®					
Inhalation Aerosol	00173-0312- 88	16.8 gm	1 inhaler	16.8 gm	*
			2 inhalers	33.6 gm	*
Genoptic ®					
Ophthalmic Ointment	00023-0320- 04	3.5 gm	1 tube	3.5 gm	*
				7 gm	7 gm
Lovenox ®					
prefilled sy- ringe	00075-0624- 30	0.3 ml	3 syringes	0.9 ml	*
			4 syringes	1.2 ml	*
				1.5 ml	*
			10 syringes	3 ml	3 ml
Metapro- terenol Inha- lation Solution	00054-8613- 11	2.5 ml	25 vials	62.5 ml	*
Xalatan ®	00013-8303- 04	2.5 ml	1 bottle	2.5 ml	*

^{*}The drug claim must be billed manually to correctly indicate decimal quantity.

19.1.7.3 Claims for Injectables –Billing Units

When billing for injectable medications such as Herceptin ®, Rituxan ®, Cyclophosphamide, etc., the actual amount provided to the client must be billed. If a partial container is provided, the quantity billed should reflect this regardless of the size of the package. If the patient only uses a partial container, the entire package can only be

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billed when no other patient uses any portion of the container and the remainder has to be discarded. Documentation of the wastage must be included in patient records.

19.1.7.4 Dispense as Written (DAW)

- a) DAW 1 represents when a physician specifies "Brand Medically Necessary" or "Do Not Substitute" or other acceptable notation. Claims for brands without FUL (Federal Upper Limit) or SMAC or for specific generic labeling may be processed using DAW 1. Refer to 19.1.3.2 Drugs, d) When a specific brand is required, for details.
- b) DAW 5 represents brand dispensed, priced as generic.
 - Federal Upper Limit (FUL). If a provider wishes to dispense a brand name product and be reimbursed at the FUL price since the generic is not available at a particular time or the "brand" is considered the provider's generic, Medicaid will reimburse these claims without prior authorizations unless Brand Medically Necessary is noted.
 - State Maximum Allowable Cost (SMAC). If the provider is willing to accept the SMAC reimbursement for a brand product (including branded generics), the provider may submit the claim with DAW 5. Products with FULs or SMACs are NOT considered part of the Generic Mandatory Program described below.
 - 3. Generic Mandatory Program No FUL or SMAC. A generic is mandatory for a brand if 2 or more therapeutically equivalent generic products are available. The provider may submit a claim without a prior authorization for drugs that meet all of the following criteria:
 - A brand product or expensive generic (branded generic);
 - No Federal Upper Limit (FUL) or SMAC for the product;
 - Part of the mandatory generic program;
 - · Submitted with a DAW 5 code; and
 - A total submitted charge less than or equal to \$30.00 (includes dispensing fee).
 - 4. Some possible options for submitting a claim for a brand or a branded generic that has been denied after submitting with a DAW 5 and receiving an alert of "PA required" are as follows:

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5. The claim can be submitted via Point-of-Sale (POS) if the provider bills and accepts the total payment of \$30.00 or less.

- A claim can be submitted after prior authorization (DHS Form 1144B) for the prescriber justifying the need for the specific branded generic is authorized. The DAW 5 code and the PA number for the branded generic must be submitted.
- 7. An "expedited" prior authorization (DHS Form 1144B) may be submitted to the Pharmacy Fiscal Agent without a prescriber signature ONLY when there is a product shortage for less expensive generics. The Pharmacy Fiscal Agent will authorize the drug if both of the following conditions are met:
 - A completed prior authorization (DHS Form 1144B) without the prescriber signature; and
 - The justification field of the DHS Form 1144B is completed with the specific language that states: "Branded generic: Less expensive generic not available from wholesaler."
- 8. For auditing purposes, it is recommended that the above justification language be documented on the prescription.
- 9. If a less expensive generic is not available at the pharmacy, the client can be referred to another pharmacy that does stock a less expensive generic.
- 10. The actual brand product may be used if "Brand Medically Necessary", "Do Not Substitute" or other acceptable notation (see 19.1.3.2 (d)) is specified on the prescription by the prescriber. The claim can be submitted with DAW 1.
- 11. Claims for brands (including branded generics) with a total charge greater than \$30.00 require prior authorization if the prescriber has not indicated "Brand Medically Necessary" or Do Not Substitute".

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c) DAW 7 represents substitution not allowed - brand drug mandated by law. If a provider dispenses anticonvulsant medications used for the treatment of epilepsy and seizures, Medicaid will reimburse these claims as brand as mandated by law.

d) Claims for Coumadin, Synthroid, and brand oral contraceptives with a Federal Upper Limit (FUL) price should be billed using DAW 7 unless the prescriber has noted brand medically necessary on the prescription. In this case, DAW 1 should be used.

19.1.7.5 Billing Procedures for Partial Filling of Prescriptions

- a) When a pharmacy provider cannot dispense the entire quantity required by a prescription due to an insufficient supply, the client may be given a partial quantity and asked to return for the remainder at a later date. In this situation, there are 2 different ways to proceed which would be acceptable to Med-QUEST Division (MQD):
 - Bill the initial partial quantity plus the dispensing fee and when the remainder is picked up, the initial claim is canceled and a new claim for the entire amount is submitted; or
 - 2. Wait until the entire quantity is dispensed before submitting a claim for payment.
- b) Under no circumstances is the MQD to be billed more than one dispensing fee.

19.1.7.6 Early Refills

- a) No payment will be made for medication refills obtained more than 7 days before the anticipated end of the previous supply based on a 30-day supply. This is a 75% utilization of the days supply. For CII Controlled Drugs, refills cannot be obtained more than 3 days before the anticipated end of the previous supply based on a 30-day supply. This a 90% utilization of the days supply. The POS system will reject all early refills. The Pharmacy Fiscal Agent will accept calls to the Help Desk concerning early refill authorizations for the scenarios listed below. If a prior authorization number is obtained, pharmacists may enter the number in the prior authorization field of their claims screen, and claims for early refills will adjudicate point-of-sale, without requiring a paper claim to be submitted to the Pharmacy Fiscal Agent. If a manual claim is submitted, state the reason for the early refill, such as:
 - 1. Change in dose.
 - 2. Additional therapy authorized.

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3. Member was readmitted to a long term care facility.

- 4. Lost or stolen medication (see additional information below).
- 5. Discharged from hospital without medication.
- b) For members who have lost their medication or had their medication stolen, a maximum of one (1) early refill per month will be allowed for controlled substances and a maximum of two (2) early refills per month will be allowed for non-controlled substances by the Pharmacy Fiscal Agent. If claims are submitted manually, "Early Refill," "Lost Meds" or "Stolen Meds" must be written across the top of the claim form.

19.1.7.7 Vacation Supply

- a) If a client is temporarily going out of state and needs a supply of medications to cover this period, a prior authorization request must be submitted for approval. If a client asks for refills of medication to be mailed to an out-of-state address, the client's assigned worker must be notified.
- b) Requests for early refills due to vacation/funeral leave etc. will be accepted by the Pharmacy Fiscal Agent prior authorization department through a faxed DHS Form 1144B. The following information must be included on the physician-signed DHS Form 1144B when submitting a request for a vacation supply:
 - 1. Medication to be filled early.
 - 2. Quantity to be filled early.
 - 3. Vacation destination (Neighbor Island will NOT be approved).
 - 4. Length of trip
- c) The authorization may not be greater than thirty (30) days in duration. The prior authorization number provided by the PA department will allow the early refill claim to adjudicate point-of-sale or submit the paper claim. The paper claim must have noted boldly across the top: "Vacation Refill."

19.1.7.8 Pharmacy Claims with Third Party Liability (TPL)

- a) General Rules
 - 1. All third party resources are primary to Medicaid. Bill the TPL first before billing the Medicaid Program.

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Medicaid payment cannot be made if the recipient failed to use their drug coverage benefit with another plan or pharmacy.

- Claims involving third parties must be billed to the Medicaid Program on hard copy claims with the TPL data entered on the claim and with the TPL payment report or denial notice attached.
- 4. If the recipient has more than one TPL, all TPL payment reports or denial notices must be attached to the claim.
- 5. Do not file via Point-of Sale (POS) system.
- b) The filing procedures for drug claims with third party liabilities are described below:
 - 1. Non-HMO Drug Plans
 - When billing Medicaid, the third party payment amount must be entered in the claim's charge column using the procedure code Z9014. The TPL payment report must be attached to the claim. The total TPL payment amount shall be subtracted from the total Medicaid allowance for all the drugs listed on the claim. We recommend each drug is billed on a separate claim when TPL payment(s) is involved, so the TPL payment(s) is applied to the appropriate drug item.
 - Federal regulations stipulate that charges made to the Medicaid Program shall not exceed the amount normally charged to the general public. Therefore, the provider adjustment (any adjustment given a third party or the recipient) must be entered on the claim with the procedure code Z9001. The provider adjustment shall be subtracted from the charges and affects payment when the net charges are less than the overall Medicaid allowance for the total claim.
 - 2. HMO Drug Plans with a HMO Pharmacy
 - Many health plans use the term co-payment, but the procedures in this section are specific to claims for recipients with drug coverage from a health maintenance organization (HMO) with an HMO pharmacy (i.e., Kaiser).
 Claims for patients with other third party plans that are not HMO with a HMO pharmacy shall be billed according to the procedures in the preceding section.
 - Federal regulations require that Medicaid payments for drug co-payments do
 not exceed the amount allowed under the Medicaid Program for the dispensed item. Therefore, HMO pharmacies submitting claims for the recipient's co-payment must identify the dispensed drugs by NDC number, quantity
 and actual charge for the item. The third party payment report must be attached to the claim.

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 The co-payment must be entered in the "MEDICAID ONLY" column followed by the letter "M". Medicaid shall pay the co-payment amount or the Medicaid allowance, whichever is lower. Your remittance advice identifies how payment was determined.

 When a fractional quantity is dispensed, enter the letter "K" to designate a HMO co-payment for fractional quantity. The metric quantity shall still be entered as "1" with actual dispensed fractional quantity, to the nearest tenth entered in the field for the name/strength of the drug. If a provider adjustment is given, the code Z9001 and provider adjustment amount shall be identified on the claim.

3. Drugs Not Covered by the Other TPL

- When the drug is not covered by the other TPL, bill with the applicable NDC number and enter Z9014 with "0.00" in the charge field. This shall cause the claim to suspend for review of the TPL denial notice that is attached to the claim.
- For over-the-counter drugs that are generally excluded under most plans, a
 TPL denial notice is not required. Enter Z9014 with "0.00" in the charge field,
 and, in the block below the address, identify the line item and note: "OTC not
 covered by ____ (TPL name)."

4. Filing Deadline Waiver Requests

- Since all available third party resources must be billed before filing for Medicaid payments, if obtaining a TPL payment affected timely billing with the Medicaid Program, you may request for a filing deadline waiver. Documentation of timely filing attempts with the third party must be indicated on the request. The request shall be sent to DHS/MQD/Finance Office, P.O. Box 700190, Kapolei, HI 96709-0190.
- c) If you have any claims filing questions, please call the ACS/PBM Help Desk at 877-439-0803. For any other questions about TPL information, please call the Third Party Liability (TPL) Program Specialist at 692-7978 or write the DHS/MQD/Finance Office, P.O. Box 700190, Kapolei, HI 96709-0190.

19.1.7.9 Other Billing Information

- a) Claims for medications are not to be submitted on the Universal Billing 04 (UB 04) form unless provided as part of an emergency room visit.
- b) All charges for drugs used in a practitioner's office for testing are included in the fee for the specific procedure; no additional allowance for the drugs will be made.

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c) Only drugs are submitted in National Drug Code (NDC) format. Durable medical equipment (DME), medical supplies, and orthotic and prosthetic devices are not drugs even if they have valid NDC numbers. Therefore, for claims submittal and requests for authorization, DME, medical supplies, orthotic and prosthetic devices must be coded using applicable and appropriate alpha numeric Healthcare Common Procedural Coding System (HCPCS) codes.

- d) All claims for drugs submitted by outpatient pharmacies, long term care pharmacies and prescribers must be coded with the NDC numbers assigned to the individual drugs. The only exception relates to compounded drugs.
- e) All drugs in the compounded product which have NDC numbers should be coded with NDC numbers and correct units. However, if any of the drugs to be compounded do not have an NDC number, the name of the drug and quantity must be provided.
- f) Claims for compounded drugs must be submitted hardcopy. Claims submitted electronically or via POS are not permitted.
- g) HCPCS codes are used for billing the actual administration of drugs. All drugs are billed using appropriate NDC numbers.
- h) For claims from Hospital Outpatient Pharmacy, see section 19.2.4, Billing.
- i) The pharmacy provider is not obligated to refund clients who have paid for prescriptions and then receive their Medicaid cards which include coverage for that time period. The MQD does not refund the client for any of their incurred expenses.
- j) The Pharmacy Fiscal Agent Help Desk is available twenty-four (24) hours a day, seven (7) days a week. The Prior Authorization (PA) Desk is available 7 days a week. The toll-free number is located in Appendix 1.

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19.1.7.10 Adjustments Requests

- a) To expedite the processing of adjustment requests:
 - Attach a copy of the remittance advice to the request with the claim number highlighted as this document contains all the necessary information to identify the claim; and
 - 2. Indicate the specific reason for the adjustment (provider number should be ____, quantity should be____, etc.). Noting "overpayment" or "underpayment" is not sufficient.
- b) Claims that a provider may feel are underpaid should be submitted with additional documentation to justify the services. Claims submitted with no additional documentation with not be considered for additional payment.

19.1.7.11 Qualified Medicare Beneficiaries (QMB) versus Dual Eligibles

- a) Under the Qualified Medicare Beneficiaries (QMB) plan, Medicaid only pays the Medicare premiums, deductibles and co-payments for the client. As such, QMB clients are only entitled to Medicare benefits. Medicare should be billed for Medicare covered medications and the clients should be charged for the drugs not covered by Medicare. A provider must be a registered with MQD as a QMB provider to be reimbursed for the deductibles on Medicare crossover claims.
- b) For clients with dual coverage, QMB and Medicaid, Medicare should be billed for the Medicare covered drugs and Medicaid for the rest. For dual eligibles, the provider does not have to be a registered QMB provider.
- c) See Chapter 3, Client Eligibility and Enrollment, for additional information.

19.1.7.12 Claims Submittal

Claims can be submitted as electronic medical claims (EMC), by hard copy CMS 1500 or DHS Form 204 – the prescription drug claim form, or through the point of sale (POS) program.

19.1.7.13 Point of Sale (POS) System

a) The POS system will be restricted to Medicaid pharmacy providers who have National Provider Identifier (NPI) numbers.

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b) Claims for the following are excluded from the POS system:

1. Patients with Third Party Liability (TPL): The pharmacy must bill the TPL first and then submit any co-payment on a hard copy DHS 204 or CMS 1500. The Medicaid Program will recover any overpayments made for claims with TPL.

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- 2. Medical supplies or Durable Medical Equipment (DME) will not be processed by the POS system;
- 3. Home infusion therapy supplies and service codes when a provider "prepares" a medication for parenteral administration such as ceftriaxone mixed into a 100cc partial fill bag for the in-home setting; See section 19.3, Home Pharmacy Services and Supplies;
- Multiple submissions of the same claim via different submission methods paper, EMC, POS;
- 5. Drugs compounded by the pharmacy;
- 6. Drugs prescribed for clients with Medicaid coupons;
- 7. Drugs prescribed for clients with "spend-down" (cost-share) requirements, if service date is prior to August 1, 2001;
- 8. Non-rebate drugs

19.1.7.14 Records

- a) Records Maintenance
 - 1. Providers under the Medicaid Program shall maintain and keep all records necessary to fully disclose the extent of services rendered to clients. Records are to be retained for a period of at least 7 calendar years and must comply with Federal retention rules. These records include the following:
 - Signature logs noting counseling and medication being dispensed to specific clients; and
 - Records of prescriptions, medications, assistive devices or appliances prescribed, ordered or furnished.
- b) Examination of Records: Med-QUEST Division may conduct a variety of audits, including patient medication verification mailings, and off-site record audits. Prescribers shall be contacted to assist with questions regarding prescriptions. A licensed pharmacist is responsible for performing and participating in all medication compli-

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ance audits, invoice audits, chart reviews and desk audits. Please be reminded of the Hawaii Revised Statutes [HRS §346-40(b)] that states, "No provider shall refuse or fail to make available access to all records to any duly authorized representative of the Department of Human Services for the purpose of examination.",(see Chapter 2).

19.1.8 Reimbursement of Pharmacy Claims

19.1.8.1 General

- a) The maximum allowance for medications is the lowest of the following:
 - 1. Single source drugs:
 - Estimated Acquisition Cost (EAC) plus a dispensing fee;
 - The billed charge; or
 - Provider's usual and customary charge to the general public.
 - 2. Multiple Source Drugs:
 - The billed charge;
 - The provider's usual and customary charge to the general public;
 - The Federal Upper Limit (FUL) price plus dispensing fee; See Appendix 1 for CMS website for the FUL price list.
 - When no FUL available, the State Maximum Allowance Cost (SMAC) plus dispensing fee(see Appendix 1 for Pharmacy Fiscal Agent website for SMAC list); or

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The Estimated Acquisition Cost (EAC) plus dispensing fee.

- 3. Over-The Counter (OTC) Drugs:
 - · The billed charge;
 - The provider's usual and customary charge to the general public including any sale item which may be available on the day of service;
 - When no FUL available, the State Maximum Allowable Cost (SMAC) plus a dispensing fee (see Appendix 1 for Pharmacy Fiscal Agent website for SMAC list);
 - The Federal Upper Limit (FUL) price plus a dispensing fee; See Appendix 1 for CMS website for the FUL price list or
 - The Estimated Acquisition Cost (EAC) plus a dispensing fee.
- b) The EAC is defined as the Average Wholesale Price (AWP) minus 10.5%., or the AWP, when the AWP is the Average Sales Price (ASP).
- c) The program shall not pay more than the general public for the same medication.
- d) If at least two therapeutically equivalent generic drugs are available in the marketplace, claims will reject a submitted brand and require a generic product.
- e) Payment will not be made for brand medications subject to the FUL when a less expensive therapeutically equivalent generic product is available and the prescriber has not specified "Brand Medically Necessary" on the prescription. If the client insists on the brand product, the client shall pay for the entire cost of the prescription.

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f) Prescriptions must be written generically to allow dispensing of the most economically priced drug products available to the pharmacist or other dispenser, pursuant to the State generic product substitution act.

- g) If the practitioner does not recall the generic name, "Substitution O.K.", "Generic Equivalent" or other similar notation may be specified on the face of the prescription.
- h) Certain products are exempt from the FUL price such as oral contraceptives, Coumadin, Synthroid and antiepileptic medications when actually used for epilepsy as stated in Part VI, Drug Product Selection of Chapter 328, HRS. When anti-seizure medications are used for other indications, therapeutically equivalent generics are to be provided unless "Brand Medically Necessary" or "Do Not Substitute" is noted on the prescription. If the provider is not sure of the diagnosis, the provider must contact the prescriber for this information. (See section 19.1.7.4, Dispense as Written).
- Claims for medications not dispensed or administered within applicable State and Federal laws will not be paid.

19.1.8.2 Dispensing Fee

- a) The State agency sets the dispensing fee based on results of surveys on the cost of pharmacy operations. This dispensing fee is added to ingredient cost when calculating payment for prescriptions.
- b) The dispensing fee for any maintenance or chronic medication shall be extended only once per 30 days without medical authorization from the program. Other appropriate limits regarding the number of dispensing fees paid per interval of time shall be determined as necessary by the program. Note the following:
 - 1. Previously permitted quantities for more than 30 days, and up to 90 days, for birth control pills are not affected;
 - 2. Previous allowance period for refills is not affected so a prescription may still be refilled up to 7 days early; (3 days for CII drugs)
 - 3. Maintenance/chronic medications dispensed on a trial basis (such as a 15 day supply) refilled for no more than 2 months are not included;

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4. New prescriptions for maintenance/chronic medications due to a direction change are not included.

c) The current dispensing fee for pharmacy providers is paid per claim. Other practitioners who dispense medications from their offices shall receive a different dispensing fee per claim. If a pharmacy is not located within 5 miles of the practitioner's office, special consideration for payment at the pharmacy rate may be made upon written request to the MQD Administrator for approval. See Appendix 1 for dispensing fee.

19.1.8.3 Clarification of One Dispensing Fee Allowable Per 30 Days

- a) Specific Quantity Determined by Prescriber
 - 1. As stated in the Hawaii Administrative Rules (HAR), the MQD will only extend one dispensing fee per 30 days for any maintenance or chronic medication. However, a specific quantity determined by the prescriber if it lasts less than 30 days will be honored. When a specific quantity (examples: 20 tablets; 1 inhaler; 100 inhalations; 15gm) is stated on the prescription, the pharmacy provider may bill a dispensing fee for each refill regardless of the time period. However, to encourage patient compliance, the prescriber should be contacted for appropriate corrections if the quantity is not adequate. Example: An ointment is to be applied to most of an adult body twice times daily and a 15 gm tube is prescribed.
 - 2. For topical products, the number entered in the "Days Supply" field on the claim should be an appropriate estimate.
- b) Quantity Determined by the Pharmacy Provider
 - When the quantity is not determined by the prescriber but is left to the discretion
 of the pharmacy provider dispensing the medication (examples: PRN; 1 tube if
 various sizes are available), Medicaid will only extend one dispensing fee per 30
 days regardless of how many times the prescription is refilled during that period.
 - 2. Examples:
 - Albuterol Inhaler 2 puffs QID prn (no quantity stipulated)

If pharmacy provider determines how many inhalers and the size of the inhaler, the MQD would only extend 1 dispensing fee per 30 days because the prescriber did not specify the size.

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Hydrocortisone Cream – apply BID prn

Dispense: 1 tube

If pharmacy provider determines the tube size dispensed, the MQD would only extend one dispensing fee per the 30 days because the prescriber did not specify the size.

19.1.8.4 Compounding Fees

- a) Compounded drug allowances are determined as follows:
 - Solutions and/or suspensions compounded from 2 liquids are reimbursed based on the cost of each solution or suspension plus the dispensing fee and a compounding fee. See Appendix 1 for fee schedule.
 - Ointments or creams compounded from two or more ointments or creams are reimbursed based on the cost of each ointment or cream plus the dispensing fee and a compounding fee.
 - Ointments or creams compounded from substances levigated into ointment or cream base are reimbursed based on the cost of each ointment or cream plus the dispensing fee and a compounding fee.

19.1.9 Hospice Care and Payments

19.1.9.1 Payment for Related Services

Clients may select Hospice care when they meet designated criteria regarding terminal illness. The Hospice provider is paid a per diem rate to cover all medical services to treat the terminal illness. Drugs to treat the terminal illness as well as drugs being used to treat the side effects of the terminal illness medication treatment are included in payment to the Hospice provider. Example: Opioids for chronic pain and stool softeners or laxatives for the constipation caused by the opioids.

19.1.9.2 Payment for Non-Related Drugs

- a) The Med-QUEST Division (MQD) will consider payment for drugs that are not related to the terminal illness. The process is:
 - 1. The Hospice provider determines if a medication is related to the terminal illness.

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 If the drug is not related to the terminal illness, the Hospice provider will submit a DHS Form 1144B with a letterhead cover sheet and indicate this is a Hospice client and the following drugs are not covered. No prescriber signature is needed but the prescriber name is required.

- 3. The DHS Form 1144B is faxed to the Pharmacy Fiscal Agent. See Appendix 1 for fax number.
- 4. The Hospice notifies the pharmacy provider that the authorization from the Pharmacy Fiscal Agent has been requested for the medication.
- 5. The results of the DHS Form 1144B review will be faxed to the "return sender fax number" Hospice indicates.
- 6. The maximum approval period will be for six months. If the client still needs the medication after six months, the Hospice needs to submit a new DHS Form 1144B.
- 7. Note: The regular prior authorization (PA) requirement for medical necessity is NOT lifted for these clients. If a regular PA is required, the pharmacy provider will be notified by the Pharmacy Fiscal Agent.
- 8. The PA review will be completed within 24 hours.

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19.2 Hospital Outpatient Pharmacy

19.2.1 Description

Pharmacy services may be provided through hospital outpatient pharmacies.

19.2.2 Amount, Duration and Scope

- a) The drug is medically necessary to treat a client's medical condition as in the following:
 - 1. Outpatient drugs used during treatment in emergency rooms;
 - 2. Take home medications for outpatient treatment in emergency rooms;
 - 3. Take home medications for inpatients being discharged from a medical facility;
 - 4. Drugs used in the renal dialysis unit;
 - 5. Drugs used in the cancer chemotherapy unit;
 - 6. Drugs used in the hospital outpatient treatment room; or
 - 7. Waitlisted skilled nursing facility (SNF) or intermediate care facility (ICF) clients who are located in the acute care area waiting for a space in the SNF or ICF area to become available.
- b) Criteria in section 19.1.2, Pharmacy Services, also pertain to this section, Hospital Outpatient Pharmacy.

19.2.3 Drug Formulary, Exclusions, Limitations, Authorization Requirements, Reimbursement of Pharmacy Claims, and Long Term Care

See Sections 19.1.3, 19.1.4, 19.1.5, 19.1.6, 19.1.7, 19.1.8, and 19.1.9, respectfully, in Pharmacy Services.

19.2.4 Billing

- a) Emergency Room
 - 1. Outpatient drugs used during treatment in the emergency room are to be billed on the hospital claim form (UB-04) under the revenue codes specific for drugs.
 - 2. Take home medications for outpatients treated in the emergency room are to be billed on the CMS 1500, DHS Drug Claim 204 billing form, Electronic Media Claim (EMC) or using the Point-of-Sale (POS) system.

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b) Inpatient Discharge

1. Take home medications for inpatients being discharged from a medical facility must be billed as part of the hospital stay on the UB-04 claim form. A maximum of seven (7) days supply of medications may be dispensed at the time of discharge. See Appendix 4 for UB04 billing guidelines.

- c) Hospital Outpatient (other than emergency room), Waitlisted SNF or ICF, and SNF or ICF
 - 1. Hospital outpatient would include such settings as a renal dialysis unit or cancer chemotherapy unit as well as hospital outpatient treatment rooms. Waitlisted SNF or ICF refers to clients who are located in the acute care area waiting for a space in the skilled nursing or intermediate care facility area to become available. SNF or ICF refers to clients who are located in the long-term care units of acute care hospitals. Medications provided in these settings must be billed on the Prescription Drug Claim 204 billing form or using the Point-of-Sale (POS) system.
 - 2. Although the prescription number is a required field on the 204 form, the field does not require validation or a set format. Therefore, since the drugs provided in the outpatient hospital, acute waitlisted SNF and ICF settings are ordered by the physicians in the patient's medical chart and no formal prescriptions are filled, a written hospital order signed by the physician is an acceptable substitute for a prescription. The facility is not required to convert a written hospital order to a hard copy prescription. Because the accuracy of claims processing is not affected and documentation of all pharmacy orders is available, the facility may assign designated prescriptions numbers. Claims may have the same number (9999) or different numbers (100, 200, 300).
 - 3. Since waitlisted SNF and ICF and hospital outpatient orders do not indicate "refills", chronic medications shall be billed once a month. Each month's billing will be considered a "new" order and must meet the requirements of a new prescription. Recertification of waitlisted SNF or ICF status must be performed each month. Thus, hospital orders for waitlisted SNF and ICF patients must be reviewed monthly.
 - 4. Billings for chronic medication shall be for the medications supplied in one month and only for medications that have been administered to the patient. Billings for antibiotics or other drugs that are indicated for specific short-term therapy (e.g. 7 days, 2 weeks) shall be submitted once after the therapy has been completed or discontinued. For injectable medications that are prepared for the patient (e.g. ceftriaxone and 5% Dextrose), the quantity of each ingredient shall be billed separately by NDC number with one dispensing fee per line item.

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5. Outpatient drugs are usually administered following protocols that may be adjusted depending on the patient's response. Therefore, if the drugs and dosages of the drugs do not change during the month, they shall be considered chronic medications and billed once a month. However, for drugs such as antibiotics and chemotherapy agents, if there is an adjustment to the drugs or dosages to the extent that a product with a different NDC number is used, the drugs with different NDC numbers used in a session do not have to be billed once during that month. If the same NDC number(s) are used, the dosages shall be totaled and billed once a month.

- Medications such as Calcijex and Infed used in conjunction with routine clinical procedures such as hemodialysis are considered chronic medications. Although the quantity may vary during the month, the total amount given per month should be calculated and billed monthly.
- If fractional quantities cannot be processed by the provider's computer software billing program, the provider must bill the fractional quantities according to the procedures that apply to compounded drugs. The Pharmacy Fiscal Agent's pharmacy consultant will review these manual claims and extend payment for the correct quantity.
- If outpatient pharmacy software is used to submit long term care (LTC) claims, unique prescription numbers may be needed. If so, the patient's medications must be renewed at the time of the physician's required evaluation such as monthly or quarterly. The renewals may be used as prescriptions and a copy of the renewals must be present in the pharmacy. Any changes to the renewals must be posted in the patients' prescription profiles. If there are no changes on the physician renewals, the order will be valid for a one month supply with refills that do not exceed State regulations. Orders for controlled substances must indicate the quantity and refill status and be in accordance with State and Federal controlled substance requirements.
- 6. The facilities where Medicaid clients reside are responsible for ensuring all prescriber telephone orders for medication are countersigned based on the facility's policies and procedures. If the facility does not provide the countersignatures timely to the pharmacy that provided the medications based on the initial telephone orders, the pharmacy can do one of the following:
 - · Repay Medicaid; or
 - Repay Medicaid and collect from the facility.

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19.3 Home Pharmacy Services and Supplies

19.3.1 Description

- a) Home Pharmacy Services and Supplies, also called Home Infusion Services and Supplies, are those services and supplies related to the administration of fluids, drugs and chemical agents intravenously in the home setting.
- b) In addition, drugs and chemical agents provided by other parenteral means (Example: Subcutaneously, epidurally) which require the use of an infusion pump and the provision of nutritional substances parenterally or enterally to Medicaid clients in the home setting are considered home pharmacy services and supplies.

19.3.2 Amount, Duration and Scope

- a) The service/supply is medically necessary to treat a client's medical condition.
- b) The therapy and therapeutic agents are non-experimental and can be safely provided in the home setting.
- c) It is medically justified to provide the service/supply in the home setting.
- d) The service/supply must be authorized on the DHS Form 1144B.

19.3.3 Limitations

- a) The client
 - 1. Must reside in a home (residence) to be eligible for this service. Services and supplies rendered during a stay in a hospital, nursing facility or other institutional setting are not reimbursable as home pharmacy services and supplies.
 - 2. Must have a physician who prescribes the services/supplies and monitors the client's response to the therapy.
 - 3. Must not require acute inpatient hospitalization.
 - 4. Must be willing and capable of safely self-administering or have a caregiver who is available, capable and willing to administer and monitor the services/supplies. The client/caregiver must have received training to administer and monitor the

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therapy and must have demonstrated the ability to the home infusion provider to follow these instructions for care.

b) The provider

- 1. Must be a participating Medicaid provider.
- 2. Must either be accredited by a national healthcare accreditation organization as a free standing home pharmacy or an acute-care hospital.

19.3.4 Authorization

19.3.4.1 General

- a) The following information should be documented on the Request for Medical Authorization (DHS Form 1144B):
 - 1. Applicable diagnosis(es).
 - 2. The specific home pharmacy service(s) being requested—Example: IV antiinfective.
 - 3. The drug(s)/agent(s) being administered, the quantity and frequency—Example: ganciclovir, 300 mg. daily.
 - 4. The reasons the service, drug, and method of delivery are medically necessary.
 - 5. The projected length of therapy.
- b) Unless clearly specified, the route of administration of the covered home pharmacy therapies must be intravenous. Generally, subcutaneous/intramuscular injections, such as insulin, growth hormone, Epogen, etc., are not included in the covered home pharmacy therapies. However, subcutaneous injections may be covered when it is medically necessary for the drug to be given with a pump (example: subcutaneous narcotics with Patient Controlled Analgesia (PCA) device). The following therapies are covered under Medicaid's Home Pharmacy benefit:
 - 1. IV hydration therapy.
 - 2. IV antibiotic, antiviral and antifungal therapy.

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3. IV, subcutaneous with PCA device and epidural chronic pain management.

- - 4. Intrathecal pain management (Implantable infusion pump).
 - 5. IV chemotherapy
 - 6. IV/Subcutaneous chelation therapy; specific IV therapy immune gammaglobulin, inotropic agents, albumin; other IV therapy—agent must be specified.
 - 7. IV catheter care for a catheter which is not in active use.
 - 8. Parenteral nutrition.
 - 9. Enteral nutrition.

19.3.4.2 Authorization Criteria (Excluding Catheter Care, Enteral and Parenteral Nutrition)

- a) The mode of therapy (intravenous, subcutaneous, epidural, intrathecal) is appropriate for the drug.
- b) The patient's condition cannot be treated with oral or intramuscular agents.
- c) The drug, quantity, frequency of administration and duration of therapy are medically appropriate.

19.3.4.3 Approval Criteria for External Infusion Pumps

- a) Infusion pumps must not be disposable and must meet at least one of the following criteria:
 - 1. There is medical need for the infusion of the drug at a controlled rate.

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2. There is medical need for the drug to be infused over an extended period of time (more than 2 hours) and not by bolus or for a shortened period of time (less than 2 hours).

- 3. Intermittent infusion by the patient is medically justified (example: PCA devices for intractable pain).
- b) If a stationary infusion pump is medically necessary, an IV pole or supply stand used with infusion pumps will be approved.

19.3.4.4 Authorization Criteria for IV Catheter Care

- a) The catheter is not in use.
- b) There is medical justification for not removing the catheter and likelihood that it will be accessed in the near future.

19.3.4.5 Authorization Criteria for Enteral Nutrition

- a) The prepared formula (example: Ensure, Jevity) must be administered through a nasogastric, gastric or other enteral tube.
- b) Prepared formula can only be authorized for oral intake if it is medically necessary in the treatment of an inborn metabolic abnormality or an abnormality of digestion or absorption.
- c) Low molecular weight prepared formula (Vivonex, Advera) can be authorized for oral use for patients who meet all of the conditions listed below:
 - 1. Extreme weight loss of 20 pounds or 10% of normal body weight over a short period of time.
 - 2. Serious diarrhea/malabsorption problems.
 - 3. Otherwise would require total parenteral nutrition.

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4. One of the following diagnoses:

- AIDS/ARC Syndrome.
- Chronic Pancreatitis.
- Inflammatory Bowel Disease.
- Regional Enteritis (Crohn's Disease).
- Short Bowel Syndrome.
- d) Enteral pumps are authorized when gravity or syringe feedings are not suitable due to reflux, dumping syndromes and other conditions associated with bolus feedings which are ameliorated with the use of an enteral pump.
- e) Enteral tubes:
 - 1. All enteral tubes need to be authorized.
 - 2. A request for authorization of more than 3 nasogastric tubes (examples: B4081-B4083) or one gastrostomy/jejunostomy tube (examples: B4084, B4085) per 3 months must be medically justified.

19.3.4.6 Authorization Criteria for Parenteral Nutrition

The patient must have a condition, which involves the gastrointestinal system and significantly impairs its ability from absorbing the nutrients needed to maintain weight and optimize bodily functions.

19.3.4.7 Reimbursement

- a) Drug:
 - 1. Drug(s) are reimbursed per general billing guidelines (See 19.1.8.1).
 - 2. An individual drug should be billed no more frequently than once per week.
 - 3. Drugs must be National Drug Code (NDC) coded. Unit values (milliliters, milligrams, etc.,) used must be those established by the National Council For Prescription Drug Programs (NCPDP) for the specific drug.
 - 4. Drugs can be submitted POS, or manually on the CMS 1500 claim form.

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b) Global Rate

1. The payment methodology for all services and supplies excluding drugs, infusion pumps or IV poles is a fixed global amount for all the services/supplies rendered per day or per dose. Global rates include but are not limited to the following: Mixing and compounding, tubing, adapters, caps, needles, filters, cannulas, cassettes, elastomeric devices, empty bags/minibags, extension sets, alcohol and povidone swabs/swabsticks, IV start kits, central venous catheter dressing kits, syringes, gloves and masks.

c) Global Rate for Multiple Therapies

- 1. When more than one antibiotic, antiviral and/or antifungal are authorized and it is clear that these must be infused separately because of incompatibility, a global rate will be paid for the first drug and a "multiple anti-infective" global rate will be paid for each subsequent anti-infective drug. If multiple drugs of different classes are authorized (Example: hydration and antibiotic), a global rate is allowed for the most costly service and 50% of the global rate for each additional service. Enteral and parenteral nutrition are paid according to Medicare criteria and are not subject to the global multiple therapy rule.
- 2. Global rates are assigned specific local payer Healthcare Common Procedure Coding System (HCPCS) codes. The description of the code indicates whether it should be billed per day or per dose and gives limits. For multiple therapies of different classes, the local payer HCPCS code for the most costly therapy shall be used and all other therapies shall be coded with the local payer code assigned to the therapy followed by the modifier –51.

d) External Non-Disposable Infusion Pumps

- The pumps covered are stationary or ambulatory non-disposable infusion pumps, pumps for parenteral nutrition and pumps for enteral nutrition. Although payments for enteral pumps differ from payments extended for external infusion pumps and parenteral nutrition pumps, the payment rules for all non-disposable pumps are similar.
- 2. The external non-disposable infusion pump may be initially purchased or rented.
- 3. When rented, the payment for the pump is based on a monthly rate if the pump is in the home for at least 15 days in the month. One half of the monthly rental will be reimbursed if the pump is in the home for less than 15 days per month—this may be applicable for the first or last month of treatment. Hawaii Medicaid's

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policy on extended rentals is a modification of Medicare's policy regarding capped rental items and is as follows:

• The monthly rental of the pump cannot exceed a total of 15 months.

- After 15 monthly rentals have been paid, the supplier must continue to provide the item without charge until the medical necessity for the pump ends or Medicaid coverage ceases.
- Maintenance and servicing will be paid no more frequently than once every six months after the 15 month rental period has ended and only when the pump is actually serviced, repaired or replaced. A DHS Form 1144B for maintenance/servicing must be approved.
- The provision of a usable pump is included in the reimbursement for the maintenance, serving or repair of the pump.
- The pump is returned to the supplier when it is no longer medically necessary.
- For initially purchased pumps, a maintenance and servicing fee is payable every six months after the manufacturer's warranty has expired and only when the pump is actually maintained, serviced or repaired. The provision of a usable pump is included in the reimbursement for maintenance, servicing and repair. A DHS Form 1144B for maintenance/servicing/repair must be approved.
- Disposable infusion pumps (elastomeric devices) are included in the global rates and not separately reimbursable.
- The use of more than one external pump must be medically justified.

e) IV Pole or Equipment Stand

1. The payment for the rental of a pole or a stand for use with a stationary nutrition pump is based on a monthly rate. The rental is counted toward the purchase.

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After six (6) months of rental, the pole/stand is paid in full. The pole is returned to the supplier when it is no longer medically necessary.

- 2. If a stationary pump is initially purchased, the pole or equipment stand can also be purchased.
- f) Reimbursement for Enteral and Parenteral Nutrition Therapy
- g) Reimbursement for enteral and parenteral nutrition therapy is based on the methodology and coding system established and used by Medicare Part B, which will be detailed in a subsequent section. If enteral and/or parenteral nutrition therapy is provided with other home pharmacy services, parenteral and enteral therapy services are paid at 100% of allowable and are not subject to the multiple therapy payment rule.

19.3.4.8 Components

The following sections describe the components of the nine (9) covered home pharmacy therapies and external non-disposable pumps and IV pole/equipment stands:

- 1. IV hydration therapy.
- 2. IV antibiotic, antiviral and antifungal therapy.
- 3. IV/Subcutaneous with PCA device and epidural chronic pain management.
- 4. Intrathecal pain management (implantable infusion pump).
- 5. IV chemotherapy.
- 6. Miscellaneous IV/Subcutaneous therapy—chelation, gammaglobulin, inotropic agents, albumin, other agents.
- 7. IV catheter care.
- 8. Enteral nutrition.
- 9. Parenteral nutrition.
- 10. Non-disposable pumps & IV poles/equipment stands.
- a) IV hydration therapy:

Drugs:

Include, but are not limited to hydration solution, electrolytes, minibags, other additives (Example: multivitamins), flushes—heparin, saline, sterile water, topical analgesics.

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Drugs can be billed no more frequently than once per week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).

Global Hydration Supply and Service Per Day:

Includes, but not limited to empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers.

b) IV Antibiotic, Antiviral and Antifungal Therapy:

Drugs:

Includes all drugs used in antibiotic, antiviral, antifungal therapy, including the specific anti-infective agent, heparin, saline, sterile water, topical analgesics, epinephrine or anaphylactic kits, minibags, etc. Drugs can be billed no more frequently than once per week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).

Global Anti-Infective Supply and Service Per Dose:

This includes empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs, swab sticks, cotton tip applicators, sharps containers, etc.

Global Multiple Anti-Infective Supply and Service Per Dose:

If more than one agent can be given together, no additional anti-infective supply fee will be extended. If there is a medical need for more than one agent to be delivered separately (examples: agents not compatible when given together, agents given on separate schedules, etc.) then a multiple anti-infective agent supply per dose can be approved. The global anti-infective supply and service per dose code should be used in billing for the more frequently administered anti-infective agent and the global code with a modifier –51 should be used for all other anti-infective agents.

c)	IV Pain	Management	Therapy:
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Drugs:

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Includes all drugs used in the IV pain management therapy, including the specific pain agent, heparin, saline, sterile water, topical analgesics, minibags, etc. Pain medication administered subcutaneously when a PCA device is medically indicated is included. As with hydration and anti-infective therapy, drugs can be billed no more frequently than once per week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).

Global IV Pain Management Supply and Service Per Day:

This includes empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers, etc.

d) Intrathecal Pain Management Therapy (only when an implanted infusion pump is used):

Drugs:

Includes all drugs used in the intrathecal administration, including the specific pain agent, heparin, saline and sterile water. As with all previous therapies listed above, drugs can be billed no more frequently than once a week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).

Global Intrathecal Pain Management Supply and Service Per Pump Fill:

This is the charge per pump fill—includes dressing kit, supplies, mixing and compounding, cassettes, etc.

Reprogramming:

This includes reprogramming of the pump upon physician order.

e) IV Chemotherapy:

- 1. Drugs:
 - Includes all drugs used in IV chemotherapy, including the specific agent(s), oral and or parenterally administered antiemetics, antinausea agents. Drugs can be billed no more frequently than once per week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).

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2. Global IV Chemotherapy Supply and Service Per Day:

Includes empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs/swabsticks, cotton tip applicators, sharps containers, chemotherapy gloves, spill kits, and disposal kits, etc.

- 3. Global Multiple IV Chemotherapy Supply And Service Per Day:
 - If more than one agent can be given together, no additional daily chemotherapy supply fee will be extended. If there is a medical need for more than one agent to be delivered separately (Examples: Agents not compatible when given together, agents given on separate schedules and the tubing, etc., cannot be reused, etc.), the daily chemotherapy supply and service code should be assigned to one (1) chemotherapy agent and the modifier –51 should be appended to all other chemotherapy agents.
- f) Miscellaneous IV/Subcutaneous Therapies
 - 1. These include but are not limited to:
 - Inotropic therapy.
 - Immune globulin therapy.
 - Albumin therapy.
 - Chelation therapy administered intravenously or subcutaneously.
 - Other agents (names must be specified).

2. Drugs:

- Includes all drugs used in the miscellaneous IV therapy, including the specific agent, heparin, saline, sterile water, topical analgesics, epinephrine or anaphylactic kits, minibags, etc. Drugs can be billed no more frequently than once a week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).
- 3. Global Miscellaneous IV/Subcutaneous Therapy Supplies and Services Per Day:

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These include empty bags/cassettes, elastomeric devices, mixing and compounding, administration sets, tubing, adapters, cannulas, extension sets, IV start sets, dressing kits, needles, syringes, alcohol/povidone iodine swabs, swabsticks, cotton tip applicators, sharps containers, etc.

- 4. Global Multiple Miscellaneous IV/Subcutaneous Therapy Supplies and Services Per Day:
 - If there is medical need for more than one agent to be delivered separately (Examples: Agents not compatible when given together, agents given on separate schedules and the tubing, etc., cannot be reused, etc.), the global miscellaneous IV therapy supply and service code should be assigned to one (1) therapy and the modifier –51 should be appended to all other therapies.

g) Catheter Care:

- 1. Drugs:
 - Includes heparin, saline and sterile water flushes, urokinase, etc. and are billable using the NDC number of the specific agents. Drugs are billable no more frequently than once per week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).
- 2. Global Catheter Care Supplies and Service Per Day:
 - Include all supplies used to maintain the patency of the catheter including but not limited to syringes, cannulas, needles and dressings.
 - Reimbursement for catheter care supplies and services are applicable only when the catheter is not in use.
 - Maximum allowable daily catheter care supplies are as follows:
 - Implanted vascular access devices (Example: Port-a-Cath) maximum of two (2) per week.
 - ii. Tunneled external vascular access devices (Examples: Hickman, Groshong, and Broviac). Protocol specific to the type of access device must be submitted at the time of request for authorization as maintenance varies significantly—Maximum of thirty (30) per month.

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iii. Peripherally inserted central catheter (PICC) and Midline Catheter— Thirty (30) per month.

- iv. Supplies in excess of the quantities cited above must be specifically authorized.
- h) Additional catheter care supplies and services which can be separately authorized and billed:
 - 1. Midline and PICC Insertion Supplies include the Midline or PICC catheter and all the supplies used in the insertion of the catheter.
 - 2. "Full Service" Midline and PICC Insertion—this includes the Midline or PICC catheter, all supplies used in the insertion of the catheter, and the skilled insertion service provided by the home infusion therapy provider.
- i) Enteral Nutrition Therapy
 - 1. Medicare coding and coding rules must be used.
 - 2. Prepared formula:
 - All formulas should be authorized and billed based on 100 calorie units dispensed per month (28 to 31 days), using the appropriate HCPCS codes.
 - 3. Enteral daily supplies:
 - Include but are not limited to all the supplies (tape, gauze, etc.) and based on three (3) separate and distinct delivery systems:
 - i. Syringe Fed
 - ii. Gravity (Bag) Fed
 - iii. Pump Fed

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• Only ONE of the three daily supply methods will be authorized. The authorized supply method is billable per day (maximum of 28 to 31 per month).

4. Enteral separate supplies:

The following supplies, if medically justified and authorized, are separately billable:

- Nasogastric, gastrostomy, jejunostomy tubes.
- Button G tube Replacement Kits.
- Bolus Extension Sets for button type tubes.
- Continuous extension sets for button type tubes.
- j) Parenteral Nutrition Therapy (PNT)
 - 1. Generally, Medicare coding and coding rules must be used for PNT. Because there is no HCPCS code for parenteral nutrition solutions with less than 10 grams of protein, if a solution contains less than 10 grams of protein is being requested, the reason must be provided (Example: Premature infant with short gut) and if medically justified, the appropriate HCPCS code should be used. Also, lipids and other additives not specified as included in the code range B4189 to B4199 and B5000 to B5200 should be coded with NDC numbers and NOT HCPCS codes.

2. Parenteral Nutrition Solutions:

- These are authorized and billable based on grams of protein using HCPCS codes.
- Parenteral Nutrition Solutions include CARBOHYDRATES, ELECTROLYTES, TRACE ELEMENTS, AMINO ACIDS and VITAMINS. Therefore, no separate billing for these are allowed.

3. Drugs:

 Additives to parenteral nutrition solutions, include but not limited to lipids and H2 blockers such as cimetidine, must be separately authorized and billed using appropriate NDC numbers. CARBOHYDRATES, ELECTROLYTES,

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TRACE ELEMENTS, AMINO ACIDS AND VITAMINS are considered part of the parenteral nutrition solution and are NOT separately billable. As with all previous drugs, drugs are billable no more frequently than once a week. Reimbursement is per general drug billing guidelines (See 19.1.8.1).

- 4. Daily Administration Kit:
 - This is authorized and billable upon approval of the Parenteral Nutrition Solution.
- 5. Daily Supply Kit:
 - This is authorized and billable upon approval of the Parenteral Nutrition Solution.
- k) External Non-Disposable Pumps and IV Poles/Equipment Stands
 - 1. The pumps covered are stationary or ambulatory
 - Non-disposable infusion pumps, pumps for parenteral nutrition, and pumps for enteral nutrition. If authorized, the pump will be reimbursed based on its specific code and following the reimbursement policy cited under REIMBURSEMENT.
- I) Specific Coding Used for Authorization and Reimbursement of Home Pharmacy Services and Supplies
 - A table that is located in Appendix 6 provides the specific coding, descriptions, and Medicaid's reimbursement rates for the global therapy service and supply codes. To expedite authorization and claims payment, the provider should use these codes.

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19.4 FACILITIES

19.4.1 Description

Medicaid participating facilities that submit claims on UB04 forms include Hospital Emergency Rooms, Home Health Agencies, Hospices, Federally Qualified Health Centers (FQHCs), Long Term Care Facilities and Dialysis Centers.

19.4.2 Services

MQD authorizes payment for prescribed legend drugs, prescribed over-the-counter (OTC) drugs, medical supplies such as gauze, needles, syringes, blood glucose strips, substances used in radiological diagnostic studies such as radio pharmaceuticals and durable medical equipment (DME) such as glucometers, canes, wheelchairs, and orthotic and prosthetic devices when submitted on the form (UB04 or CMS 1500) appropriate for the facility and participant coverage.

19.4.3 Submittal Criteria

19.4.3.1 NDC Criteria

- a) Correct NDC information is required when submitting claims, including the UB04 form, for prescribed drugs. To expedite the accurate payment of claims, MQD advises providers to:
 - 1. Verify the submitted NDC numbers are valid 11 digit codes and in the correct format. Example: 00002001102.
 - 2. When submitting claims:
 - NDC numbers must be preceded by "N4", and all leading zeros (0s) of the NDC must be included.
 - NDC quantities and UNITS, as determined by CMS, must be used: UN = unit or each; ML = milliliter; GR = gram; F2 = international unit (IU).
 - Note: Providers are not to use NDC information when billing for medical supplies, diagnostic supplies or DME.

19.4.3.2 Criteria for Hospital Emergency Room

For Medicaid only clients, Medicaid clients with Private Health Insurance and Dual Eligible (Medicare/Medicaid) clients, submit claims with the additional required NDC information on UB04 forms to the Medical Fiscal Agent for processing.

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19.4.3.3 Criteria for Other Hospital Outpatient Services

a) For Medicaid only clients, do NOT submit NDC information on UB04 to the Medical Fiscal Agent. Submit CMS 1500 or DHS 204 forms with correct NDC information to the Pharmacy Fiscal Agent for drugs that are separately billable.

- b) For Medicaid clients with Private Health Insurance, do NOT submit NDC information on UB04 to the Medical Fiscal Agent. Submit CMS 1500 or DHS 204 forms with correct NDC information to the Pharmacy Fiscal Agent for drugs that are separately billable and covered by the primary insurer.
- For Dual Eligibles, do NOT submit NDC information on UB04 to the Medical Fiscal Agent for drugs not billable under Medicare Outpatient Prospective Payment System (OPPS).

19.4.3.4 Criteria for Home Health Agencies, Hospices, Federally Qualified Health Centers (FQHC) and Long Term Care Facilities

- a) For Medicaid only clients, do NOT submit NDC information on UB04 to the Medical Fiscal Agent. Submit CMS 1500 or DHS 204 forms with correct NDC information to the Pharmacy Fiscal Agent for drugs that are separately billable.
- b) For Medicaid clients with Private Health Insurance, do NOT submit NDC information on UB04 to the Medical Fiscal Agent. Submit CMS 1500 or DHS 204 forms with correct NDC information to the Pharmacy Fiscal Agent for drugs that are separately billable and covered by the primary insurer.
- c) For Dual Eligibles, do NOT submit NDC information on UB04 to the Medical Fiscal Agent. Submit claims to the beneficiary's Medicare Part D plan. For Part D excluded drugs, submit CMS 1500 or DHS 204 forms to the Pharmacy Fiscal Agent with correct NDC information.

19.4.3.5 Criteria for Dialysis Centers

a) For Medicaid only clients, submit NDC information on UB04 to the Medical Fiscal Agent for Epoetin alpha only. Submit CMS 1500 or DHS 204 forms with correct NDC information to the Pharmacy Fiscal Agent for all other drugs that are separately billable.

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b) For Medicaid clients with Private Health Insurance, submit NDC information on UB04 to the Medical Fiscal Agent for Epoetin alpha only. Submit CMS 1500 or DHS 204 forms with correct NDC information to the Pharmacy Fiscal Agent for all other drugs that are separately billable and covered by the primary insurer.

c) For Dual Eligibles, do NOT submit NDC information on UB04 to the Medical Fiscal Agent for drugs not billable under Medicare's dialysis benefit.

19.4.3.6 Specific Form Instructions

- a) UB04 Forms, both electronic and hard copy
 - For Revenue Code 25X, HCPCS codes are optional. However NDC numbers and quantities must be submitted. Multiple NDC numbers and quantities can be submitted for each 25X code.
 - 2. For all other Revenue Codes, providers must submit a HCPCS code in Form Locator 44.
 - 3. NDC quantity and unit must be used for NDC number information. NDC numbers are required for all drugs regardless of the Revenue Code billed.
- b) CMS 1500 Forms, both electronic and hard copy
 - For Medicaid only clients, do NOT submit NDC information on CMS 1500 to Medical Fiscal Agent. Submit NDC information on CMS 1500 or DHS 204 to Pharmacy Fiscal Agent.
 - 2. For Medicaid clients with Private Health Insurance, do NOT submit NDC information on CMS 1500 to Medical Fiscal Agent. Submit NDC information on CMS 1500 or DHS 204 to Pharmacy Fiscal Agent.
 - For Medicare/Medicaid Dual Eligibles, submit NDC information on CMS 1500 to Medical Fiscal Agent for drugs covered by Medicare Part B and not selfadministered by client.

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4. HCPCS code must be provided for each drug provided.

- 5. If a single HCPCS code is associated with multiple NDC numbers for the same date of service, providers are encouraged to use the following HCPCS modifiers:
 - KP = First drug of a multiple drug unit dose formulation; and
 - KQ = Second or subsequent drug of a multiple drug unit dose formulation.
- 6. NDC quantity and unit must be used for NDC information.